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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,678	08/01/2003	Orest W. Blaschuk	100086.401C18	4036
500	7590	02/08/2005	EXAMINER	
SEED INTELLECTUAL PROPERTY LAW GROUP PLLC			KAM, CHIH MIN	
701 FIFTH AVE			ART UNIT	
SUITE 6300			PAPER NUMBER	
SEATTLE, WA 98104-7092			1653	
DATE MAILED: 02/08/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/632,678	<b>Applicant(s)</b> BLASCHUK ET AL.	
	<b>Examiner</b> Chih-Min Kam	<b>Art Unit</b> 1653	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 January 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8,34-38,53 and 54 is/are pending in the application.
- 4a) Of the above claim(s) 1-8,36-38,53 and 54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 34 and 35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 August 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group II, claim 34 in the response filed January 7, 2005 is acknowledged. The traversal is on the ground(s) that there would be no undue burden to search Group III since Groups II and III each relate to the use of the very same cell adhesion modulating agents of claim 8 for modulating the activity of the very same cell type, vascular smooth muscle cells. The response has been considered and found persuasive, thus claims 34 and 35 are examined. Claims 1-8, 36-38 and 53-54 are non-elected inventions and are withdrawn from consideration.

### ***Informalities***

The disclosure is objected to because of the following informalities:

2. Figs. 12A-D are objected to because of the dark background, the images of these drawings are not readable; and in the drawings of Figs. 30A and 30 B, it appears there is only Fig. 30B but not Fig. 30A. Appropriate correction is required.

### ***Claim Objections***

3. Claims 34 and 35 are objected to because they are dependent from non-elected claims, claim 1 and 8. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 34 and 35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 34 and 35 are directed to a method of modulating vascular smooth muscle cell migration or apoptosis by contacting a vascular smooth muscle cell with a cell adhesion modulating agent of formula  $Z_1\text{-Cyclo(X-His-Ala-Val-Y)-Z}_2$ , where  $Z_1$  and  $Z_2$  are amino acid residues and each range from 1 to 10 residues, X and Y are each amino acid residue and a disulfide bond is formed between X and Y. While the specification indicates that the invention is directed to a method for modulating the behavior such as proliferation, migration and/or survival of vascular smooth muscle cell (VSMC) comprising contacting a cadherin expressing VSMC with a cell adhesion modulating agent of formula  $Z_1\text{-Cyclo(X-His-Ala-Val-Y)-Z}_2$  (page 13, lines 19-24; page 101, lines 18-25), the specification does not disclose a method of modulating (increasing or decreasing) vascular smooth muscle cell migration or apoptosis by contacting the cell with a cell adhesion modulating agent. The specification only demonstrates inhibition of VSMC migration (Example 23; Figs. 45A and 45B) or increasing VSMC apoptosis during migration (Example 24; Figs. 46 A and 46B) using the cadherin-modulating agent, Ac-cyclo(CHAVC)-NH<sub>2</sub>. There is no example indicating a cadherin-modulating agent of formula  $Z_1\text{-Cyclo(X-His-Ala-Val-Y)-Z}_2$  can modulate (i.e., enhance) VSMC migration and (i.e., decrease) VSMC apoptosis. The lack of description in the method of

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modulating VSMC migration and/or apoptosis using the cell adhesion modulating agent of formula  $Z_1$ -Cyclo(X-His-Ala-Val-Y)- $Z_2$  as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 34 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 34 and 35 are indefinite because the claim lacks an essential step in the method of modulating vascular smooth muscle cell migration or apoptosis. The missing step is an effective amount of the cell adhesion modulating agent used.

***Conclusion***

6. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.  
Patent Examiner

A handwritten signature in black ink, appearing to be 'Chih-Min Kam', followed by a long horizontal line extending to the right.

CMK  
February 2, 2005